

## § 170.210

### **§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.**

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

(a) *Encryption and decryption of electronic health information*—(1) *General*. Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140-2 (incorporated by reference in § 170.299).

(2) *Exchange*. Any encrypted and integrity protected link.

(b) *Record actions related to electronic health information*. The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an indication of which action(s) occurred and by whom must also be recorded.

(c) *Verification that electronic health information has not been altered in transit*. *Standard*. A hashing algorithm with a security strength equal to or greater than SHA-1 (Secure Hash Algorithm (SHA-1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180-3 (October, 2008)) must be used to verify that electronic health information has not been altered.

(d) *Record treatment, payment, and health care operations disclosures*. The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

### **§ 170.299 Incorporation by reference.**

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is avail-

## 45 CFR Subtitle A (10-1-11 Edition)

able for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the sources listed below.

(b) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677-7777 or <http://www.hl7.org/>.

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA; Telephone (610) 832-9585 or <http://www.astm.org/>.

(1) ASTM E2369-05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(2) ASTM E2369-05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

## Department of Health and Human Services

## § 170.300

(d) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; Telephone (480) 477-1000; and Facsimile (480) 767-1042 or <http://www.ncdp.org>.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(3) [Reserved]

(e) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202-3012; Telephone (317) 423-5558 or <http://loinc.org/>.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594-5983 or <http://www.nlm.nih.gov/>.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) [Reserved]

(g) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch—Informatics 1600 Clifton Road Mailstop: E-62 Atlanta, GA 30333.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(4) [Reserved]

(h) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786-3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(i) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899-8930, <http://csrc.nist.gov/groups/STM/cmvp/standards.html>.

(1) Annex A: Approved Security Functions for FIPS PUB 140-2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) [Reserved]

(j) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, <http://www.hitsp.org>

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

### Subpart C—Certification Criteria for Health Information Technology

SOURCE: 75 FR 44651, July 28, 2010, unless otherwise noted.

#### § 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.